Summary of risk management plan for Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete (Olanzapine)

This is a summary of the risk management plan (RMP) for Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete. The RMP details important risks of Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete, how these risks can be minimised, and how more information will be obtained about Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete 's risks and uncertainties (missing information).

Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete should be used.

Important new concerns or changes to the current ones will be included in updates of Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete 's RMP.

I. The medicine and what it is used for

Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete is authorised in adults for the treatment of schizophrenia.

Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response.

Olanzapine is indicated for the treatment of moderate to severe manic episode.

In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder.

It contains Olanzapine as the active substance, and it is given by oral route of administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete, together with measures to minimise such risks and the proposed studies for learning more about Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete 's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	• Weight gain • Glucose dysregulation • Dyslipidaemia
Important potential risks	• Increased risk of cardiac death (presumed sudden cardiac death)
Missing information	• None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Olanzapin Devatis 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg filmom obložene tablete.